THE INFLUENCE OF THE BMGIM MUSIC THERAPY METHOD IN THE REDUCTION OF STRESS IN PATIENTS WITH INFLAMMATORY BOWEL DISEASE (CROHN'S DISEASE AND ULCERATIVE COLITIS): QUANTITATIVE AND QUALITATIVE STUDY

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MATERIAL AND METHODS.

The different aspects related to the material and the methodology used in the study was described

Type of study.

It is a longitudinal, prospective, quantitative, analytical and experimental study, through a clinical trial by intent to treat.

Sample. The candidates to participate in the study was adults (with ages from 18 years old) diagnosed of IBD (EC and UC) in remission phase, who are treated in the Digestive Pathology Service of the General University Hospital of Valencia, who was receiving the usual treatment for this ailment. In addition, if necessary to reach the sample size, patients from other hospitals in the city of Valencia was contacted.

Patients with a score <5 in the Harvey-Bradshaw Index, and for UC those patients with a score <11 in the modified Truelove-Witts Index or a partial May Index <2, was considered referral for CE.

The final population with which it is intended to have the study is 50 patients, which was divided into two working groups: a control group (25 patients) that will receive the usual medical treatment, and another intervention-experimentation (25 patients) that will receive the usual medical treatment and will also be applied to music therapy sessions BMGIM.

Inclusion-exclusion criteria

As for the inclusion and exclusion criteria, these was the following:

- Inclusion criteria: Patients older than 18 years diagnosed with IBD in the remission phase, who do not have any extra pharmacological treatment, who attend the hospital collaborating with the study, in this case, the General Universitario Hospital of Valencia and who accept to participate in the study.
- Exclusion criteria: Those patients who do not meet the requirements of the inclusion

criteria, or who show rejection of this type of therapy. The presentation of an outbreak during the phase of the Music Therapy intervention that requires new medical treatments or adjustment of the previous ones will also be an exclusion criterion.

Procedures

The proposal of the study to be carried out follows the following steps:

- The hospital involved in the study was informed by means of a written document, of the objectives of the study, of the methodology with which it was carried out, as well as of the needs, with the objective that it be evaluated by the ethical committee of said hospital and the research project is admitted.
- A document was provided to the physicians responsible for the Digestive Pathology Service, in which the study was explained, in order to define the criteria for inclusion in it.
- A model of informed consent was provided to patients with IBD in the remission phase who are candidates to participate in the study. Once accepted by the patients, the corresponding Activity Index was made to confirm that they meet the inclusion criteria and the data collection document (CRD) was completed. In addition, a quality of life survey adapted to IBD, IBDQ9 (CCVEII-9) was conducted, as well as the questionnaire on the alteration of activities and labor productivity (WPAI). In parallel, capillary hair with a minimum size of 3 centimeters was obtained from all patients, and the level of cortisol, a hormone intimately related to stress, was obtained through the ELISA technique protocol (Enzyme-linked immunosorbent assay) using in each case the specific commercial kit, and using in the specific case of cortisol, a previous technique to extract it from the hair. In the same way, a saliva sample was obtained, from which the quantification of cortisol was obtained by the same method mentioned above (ELISA technique).
- Before applying the music therapy intervention using a group adaptation of the BMGIM method, the two groups were formed. Patients was assigned to one of the two groups randomly in a randomized manner. The intervention group will have eight sessions based on a group adaptation of the BMGIM method of music therapy, with the other group not being operated on as a negative control group. In the intervention group, work groups of 6 to 8 participants were formed with the objective of giving attention to each of the participants, as well as facilitating the task of the therapist. The study last for 8 weeks,

with an intervention of 1 hour and a half per week, with a total of 8 sessions. Meanwhile, the control group was in the hospital center without carrying out any activity.

- After the intervention with Music Therapy, in both groups the same interview was carried out and therefore the patients participating in the study was reassessed with the same scale and measures that were used prior to the intervention with Music Therapy (Activity and IBDQ). The analysis of new samples of hair and saliva will also be repeated, in order to assess the evolution of the stress level of the two months of intervention.
- Next, the analysis of the results obtained was carried out.
- Finally, this project will culminate with the writing of the doctoral thesis.

Variables

The variables that was used in this study was the following:

- <u>- Sociodemographic</u> (Age, Sex, Type of IBD, Activity Index (Harvey-Bradshaw Index or modified Truelove-Witts Index), Activity Index (Harvey-Bradshaw Index or modified Truelove-Witts Index).
- Basal variables:
- biological markers
- 1. IgA in Saliva
- 2. Cortisol level in hair.
- 3 Cortisol level in saliva
- Psychological measures

Short-form Questionnaire on Quality of Life in IBD (CCVEII-9)

Hospital Anxiety and Depression Scale (HADS)

The MOOD questionnaire

- Variables after the therapeutic application:
- biological markers
- 1. IgA in Saliva
- 2. Cortisol level in hair.
- 3. Cortisol level in saliva.
- Psychological measures

Short-form Questionnaire on Quality of Life in IBD (CCVEII-9)

Hospital Anxiety and Depression Scale (HADS)

The MOOD questionnaire

Statistical analysis of the data obtained

The statistical analysis of the data was made by means of the statistical packages SPSS (version 20) and EQS (version 6.2.). For the study of the data, the following statistical procedures were used, taking into account the nature of the variables analyzed:

- Descriptive analysis: A descriptive and differential analysis of the sample was carried out, the statistics used for this was: the mean, the median, the frequency, the percentage and the asymmetry coefficient. Analysis of covariance (ANCOVA) was then performed to determine the effect of treatment on the study variables. The pretest scores were used as covariates, the type of treatment as between-subject factor, and the post-test scores as the dependent variables. Before the ANCOVA, we verified 3 assumptions before use: 1) that the covariate variable had a statistically significant effect on the post-test treatment score; 2) the nonexistence of a statistically significant effect between the covariate variable and the independent variable treatment; and 3) the homogeneity of the regression slopes.
- Reliability and validity of the scales used: Reliability was studied by calculating Cronbach's alpha index. However, given that this index does not take into account the influence on the reliability of the rest of the constructs, the coefficient of composite reliability (CFC) and the average variance extracted (AVE) was calculated. For the study of the validity of the scale, factorial validity, convergent and discriminant validity, content validity and criterion validity was analyzed.

Ethical considerations

The study was approved by the Ethics Committee of Hospital General Universitario de Valencia and conducted according to the basic principles of biomedical research set out in the Declaration of Helsinki. Written informed consent was obtained from all participants before the study began.